DON TUITE | ANALOG/POWER EDITOR don.tuite@penton.com

Conforming With Worldwide Safety And EMC/EMI Standards

Planning to sell your mains-powered product around the world? Then saddle up, because it takes more than approved components and a checklist to get those all-important marks.

Many designers think meeting the worldwide safety standards for power supplies in mains-powered products involves following a simple checklist to ensure their designs don't run into distribution problems in some countries due to a lack of dotted i's or crossed t's. But that's a naive perspective. The truth is that most designers need some serious hand-holding during their first several designs. This task can't be addressed with a checklist and a positive attitude.

Also, safety is critical, since you don't want to electrocute your end user. Yet basic safety is the least of your worries. In fact, it isn't too difficult to demonstrate conformity if you use already-approved components, except in the case of medical products.

The catch is that the safety requirements are in the same standards as electromagnetic-compatibility (EMC) and electromagnetic-interference (EMI) requirements. You won't know if your product has any problems in those areas until you run the tests at the testing labs, and then you have to solve the problems ad-hoc in real time.

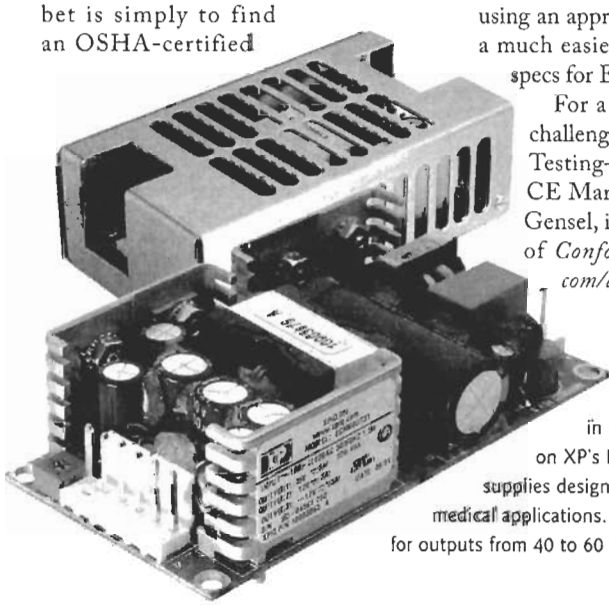
That's why you should ask experts questions about your specific situation and follow their recommendations. Your best bet is simply to find an OSHA-certified (Occupational Safety and Health Administration) nationally recognized testing laboratory (NRTL) or the equivalent overseas. One NRTL is Underwriters Laboratories (UL) itself. However, a number of others can be found on the UL Web site, any of which can test for UL certification. There's a parallel path for overseas approval. Allowing for deviations that are familiar to the experts, the fundamental requirements remain the same.

The markings for your product will differ in each country. Core standards for power-supply safety and electromagnetic compatibility and interference are the European IEC 60601 (Measurement, Control, and Lab Equipment) and 60950 (Information Technology Equipment) standards, including their various dash-numbered subparts. In the U.S., they get "UL" prefixes. In Europe, they get "EN" (for "European Norm") prefixes.

EMC AND EMI PROTECTION

There's more to these marks than electrical safety. Industry guru Derek Krous, who has gone through a number of certifications, says obtaining UL's blessing for the electrical safety of a new product using an approved power supply is usually a much easier process than meeting the specs for EMC and EMI.

For a detailed description of the challenges involved, check out "EMC Testing—Immunity Testing for the CE Mark," a long article by Rodger Gensel, in the March 15, 2007, issue of *Conformity* at *www.conformity.com/artman/publish/printer_166.shtml*. This magazine is unique in focusing exclusively on the engineering and politics involved in meeting government standards around the world. In his article, Gensel focuses on European EMI requirements. But as in the case of electrical safety, there's more overlap than difference these days.



In XP's application brief, the final power supply used in its case history was based on XP's ECM series of small-footprint supplies designed for rapid qualification in medical applications. These apps can be configured for outputs from 40 to 60 W.

Essentially, Gensel says the European Union requires manufacturers of electronic equipment to meet the EMC guidelines of EC Council Directive 89/336/EEC. The test requirements are issued by CENELEC, the European Committee for Electrotechnical Standardization.

Generic immunity standards are called out in EN 61000-6-1 and EN 61000-6-2, and generic emission requirements in EN 61000-6-3 and EN 61000-6-4, and sometimes there may be specific test requirements as well. The International Electrotechnical Commission (IEC) creates "Basic Standards" that define the specific tests, test methods, setups, and test equipment.

As with safety, you get European Norms for EMI. If you want to look them up, they're EN 61000-4-2, Electrostatic Discharge; EN 61000-4-3, Radiated EM Field; EN 61000-4-4, Burst-Electrical Fast Transients (EFT); EN 61000-4-5, Surge; EN 61000-4-6, Conducted Radio Frequency Disturbances; and EN 61000-4-8, Power Frequency Magnetic Field.

As if that weren't complicated enough, achieving conformity takes a major leap in complexity when it comes to matching power supplies to medical electronics. XP Power explains how that works in terms of the way that product safety and EMI come together in an applications brief, "Power Supplies in Medical Electronics," available at *www.xppower.com/pdfs/MedicalPowerSupplies.pdf*.

According to XP, medical equipment combines the risk of electric shock with EMC, both in terms of immunity and emissions, as critical issues. "As a result, the design of power supplies for use in the medical industry is driven as much by leg-

islation as it is by the technical requirements of powering the end equipment," the brief explains.

"System designers therefore need an understanding of this legislation and of the markets into which their products will be sold if power solutions are not to be over-specified, over-engineered, and excessively expensive as a result of building in too much safety margin when it comes to meeting legislative requirements," it continues.

The brief goes on to reference EN 60950 and the European, U.S., and Canadian variants of IEC 60601-1. It then has something interesting to say about safety levels: "The degree of protection needed in any particular medical application is related to the proximity of equipment to the patient, equipment that is directly applied to patients needing the highest specification with respect to isolation."

XP recommends three progressive safety levels to consider regarding isolation and protection when designing medical electronic equipment:

- The basic safety requirements of EN60950 that apply to all mains-connected electronic equipment
- The more rigorous IEC60601-1 standard for equipment used in patient vicinity
- The requirement for an additional isolation barrier in equipment that is in intentional physical contact with patients.

"Levels of Protection" (LOPs) are used to define the safety specifications for all electronic equipment, according to XP. Insulation or a protective earth and fuse can provide an LOP. Insulation is defined as one of five types with varying LOP ratings *(see the table)*. XP also says that an earth can be similarly classified as functional or protective, with no protection provided by a functional earth and one level of protection by a protective or fused earth.

According to the brief, the basic principle is to provide two LOPs against electric shock. Each insulation type is defined in terms of air clearance and creepage distances. *(For definitions of terms like "creepage," see the sidebar "A Brief Safety Lexicon: Selected Definitions From EN 60950," p. 42.)*

The brief gets into more specifics, dealing with fine-grain differences between EN 60959 and EN 60601-1 and current leakage specs depending on the specific kind of medical equipment in terms of whether it never touches the patient, whether it just touches the outside of the patient, or whether it gets stuck inside the patient.

The brief concludes with a case history that provides a sense of where you can expect a "semi-custom" approach, in which some elements of a power supply are preapproved to work, and to what extent the design remains a work-in-progress through conformity testing. The final power supply in the case history was based on XP's ECM series of small-footprint supplies designed for rapid qualification in medical applications that can be configured for outputs from 40 to 60 W *(see the figure)*.

The only output used from the supply provides a nominal 13.8 V. That meant the only power elements requiring safety and EMC/EMI testing and approval were the battery charger/monitor and the dc-dc converters that provided +5, +12, and +24 V to run the product itself.

So in addition to your test lab, your power-supply vendor is an excellent source of information about global safety and EMC/EMI conformity and conformity testing.

UPCOMING CHANGES

Beyond that, there's a further catch. An upcoming third edition of IEC 60601-1 will introduce several new concepts to the medical approval process later this year or maybe next year *(see "Evolving Standards Reshape Medical Power Supplies" at http://powerelectronics.com/power_systems/switch_mode_power_supplies/medical-power-supplies-standards-0407/index.html)*.

According to Peter Resca and Dave Murray of Astrodyne, these new concepts first and foremost will include risk management, followed by "essential performance." New testing and design processes will be required to support these approaches. As a result, the certification process will be more about the manufacturer identifying potential hazards and documenting how they're addressed and less about type tests with defined limits, though they will still be important, too.

"Essential performance identifies operating characteristics that can impact the safety of operators or patients. This will tie into the risk analysis performed under the risk-management system employed with the new standard," say Resca and Murray. "The purpose is to allow the manufacturer to identify the appropriate levels to ensure safe medical devices. In some cases, this may be a reduction in limit from the current standard, but in many cases it will require additional protection or analysis."

But wait—there's more. The new standard introduces the concept of means of protection, which describes the isolation protection between the electrically charged circuitry and any equipment that may come in contact with the device. Resca and Murray also note that isolation protection includes the creepage/clearance distances, insulation, and protective earth connections.

Resca and Murray further separate the means of protection into means of operator protection (MOOP) and means of patient protection (MOPP). These classifications provide greater protection for patients who may be more vulnerable to the medical device in use. MOOP is more closely aligned to the traditional IEC 60950, the standard of protection for information technology equipment (ITE).

In 2007, Resca and Murray noted that we were as many as three years away from adopting the third edition of IEC 6061-1, though MOP, MOOP, and

How Levels Of Protection (LOPs) Can Be Added To Electronic Equipment

Reference	Earth type	LOP
FE	Functional	0
PE	Protective	1
Reference	**Insulation**	**LOP**
OP	Operational	0
B	Basic	1
S	Supplementary	1
D	Double	2
R	Reinforced	2

MOPP have likely evolved in the meantime with regard to risk management.

PRACTICAL DESIGN FOR SAFETY

Of course, meeting these safety standards is critical. But what about making the design actually safe?

There is a document available online that meshes with these standards. Yet as I've been at pains to point out, simply following it won't guarantee that you will be able to sell your product in the markets you wish, though following its advice is the practical counterpart of understanding the bureaucracy. So additionally, you should check out a Texas Instruments seminar known as "Safety Considerations in Power Supply Design." It's the work of TI's Bob Mammano and UL's Lal Bahra, and it's available online at *http://focus.ti.com/lit/ml/slup227/slup227.pdf.*

Key Conformance Marks In Electronic Design

All products have to meet various regulatory compliance requirements for safety, emissions, and other criteria before they can be sold globally. All industrial nations require specific marks on products before they can be sold there. Testing and certifying compliance are the keys to getting those marks. For electronic products, safety and electromagnetic compatibility (EMC) and electromagnetic interference (EMI) are key certification issues.

In the U.S., the Federal Communications Commission (FCC) dictates the testing requirements for EMC and EMI. Products can be Class A, marketed for commercial or industrial use and not intended for home use, or Class B, targeting home use. Class B requirements tend to be more strict than Class A requirements.

Stateside, the registered certification marks of Underwriters Laboratories (UL) mean that UL or a nationally recognized testing laboratory (NRTL) has tested and evaluated representative samples of the product and determined that it meets UL's specified product safety requirements *(a)*. The negative impact of lacking a UL mark may be more de facto than de jure, but it's just about as crippling.

The Occupational Safety and Health Administration won't let products without the mark be used in businesses. Also, under the National Fire Code, electrical inspectors won't allow the product to be installed in buildings. You may be obligated contractually to have a UL mark on your product, or some customers might not sell it. And, savvy consumers look for the UL mark on products they buy.

In Europe, it's cut and dry. All products must have a CE or "Conformite Europeenne" mark *(b)*. The CE mark is all-inclusive. It shows that the product complies with the "essential requirements" of European laws or directives. It also indicates the product's conformance to legal requirements with respect to safety, health, the environment, and consumer protection in the European Union.

The marking is mandatory for certain product groups, but it can be achieved either by using an external test house like an NRTL in the U.S. or by a company's internal self-certification process. This includes companies in the U.S. A great deal of information on the subject is available from the U.S. Department of Commerce at *www.export.gov/cemark/index.asp*.

For Canada, standards are determined and required by law by the Standards Council of Canada (SCC). In general, products require the cUL, a mark from UL, expressly for Canada *(c)*. Products also require the Canadian Standards Association (CSA) mark. U.S. FCC approval is generally accepted for emissions.

UL issues the Recognized Component mark *(d)* or its Canadian variant to transformers, relays, and other subcomponents of power supplies. Using recognized components in your power supply doesn't guarantee conformance. That's where clearance and creepage and all of the other good practices, along with EMC/EMI performance, come in. But it does provide a foundation.

Japan uses the Voluntary Control Council for Interference by Information Technology Equipment (VCCI) mark, which certifies EMI compliance *(e)*. It also employs the Denan/PSE mark, which targets electrical safety *(f)*. "Denan" comes from "denki youhin anzen hou," as denki means "electrical," and anzen means "safety."

Korea's Ministry of Information and Communication offers the MIC mark *(g)*. Most MIC standards are based on IEC standards. Taiwan's Bureau of Standards, Metrology and Inspection offers the BSMI mark *(h)*. The China Compulsory Certificate (CCC) integrates the former "CCIB" Safety Mark and the "CCEE" (also known as the "Great Wall" Mark) for electrical commodities *(i)*. Several agencies on the Web offer help in obtaining the CCC.

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(a) (b) (c) (d) (e) (f) (g) (h) (i)

A Brief Safety Lexicon: Selected Definitions From EN 60950

- Basic insulation: Insulation to provide basic protection against electric shock.
- Bounding surface: The outer surface of the electrical enclosure.
- Class I: Equipment where protection against electric shock is achieved by using basic insulation, also providing a means of connecting to the protective earthing conductor in the building wiring if the basic insulation fails.
- Class II: Equipment in which protection against electric shock does not rely solely on basic insulation, but in which additional safety precautions, such as double insulation or reinforced insulation, are provided.
- Clearance: The shortest distance between two conductive parts, or between a conductive part and the bounding surface of the equipment, measured through air.
- Clearance distance: Shortest distance in air between two conductive elements.
- Creepage distance: The shortest path between two conductive parts, or between a conductive part and the bounding surface of the equipment, measured along the surface of the insulation.
- Double insulation: Insulation comprising both basic insulation and supplementary insulation.
- Functional insulation: Insulation needed for the correct operation of the equipment.
- Hazardous energy level: A stored energy level of 20 J or more, or an available continuous power level of 240 V A or more, at a potential of 2 V or more.
- Hazardous voltage: A voltage exceeding 42.4 V peak or 60 V dc, existing in a circuit that does not meet the requirements for either a limited current circuit or a telephone network voltage (TNV) circuit.
- SELV circuit (safety extra-low voltage): A secondary circuit that is so designed and protected whereby, under normal and single fault conditions, its voltages do not exceed a safe value (definitely less than 42.4 V peak or 60 V dc).
- Touch current: Electric current through a human body when it touches one or more accessible parts.
- Tracking resistance: Evaluation of insulating materials by determining their creepage distance formation (accomplished by dripping a watery solution onto a horizontal surface so that it leads to electrolytic conducting).
- Rated and surge voltages: The "rated" voltage is the value above which the creepage distance is measured. The "surge" voltage is a test impulse of short duration with a specified impulse form and polarity that is applied to test insulation paths.